

APR 17 2003

*K030927*

## **510(k) SUMMARY**

Submitted For: **COPIOUMED INTERNATIONAL, INC.**

Submitted By: **TUCKER & ASSOCIATES**  
Official Correspondent for COPIOUMED  
**JANNA P. TUCKER**, President-CEO  
198 Avenue de la D'emerald  
Sparks, NV 89434-9550  
Phone: 775-342-2612  
Fax: 775-342-2613  
E-Mail: [Tuckerjan@aol.com](mailto:Tuckerjan@aol.com)

Date of Submission: 19 March 2003

Device Name: **POWDERED VINYL EXAM GLOVES,  
WHITE**  
Class I Device, 80LYZ

Proprietary Name: (Multiple Private Labels)

Labels/Labeling: This device will be marketed to healthcare professionals at  
Dentist and Doctor Offices, Laboratories, Clinics and  
Hospitals through its distributors for the intended use.

Intended Use: A patient examination glove is a disposable device intended  
for medical purposes that is worn on the examiner's hand  
or finger to prevent contamination between patient and  
examiner.

Substantial Equivalence: Both in its intended use and/or physical  
characteristics, this device is equivalent to devices  
currently marketed by U.S. companies. Except for U.S.P.  
powder, it is the exact same glove manufactured in  
approved 510(k) **K021961**.

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Test Results (Means  
and/or Successful  
Results:

This device has met or exceeded the following  
standards and/or tests:

ASTM D 5250-00E4

ASTM D 5151-99

ASTM D 6124-01

ISO 2859

MIL Std 105E

Bio-Compatibility:

Dermal Sensitization

Primary Skin Irritation

Bio-Burden (Procedure Method 8315)

Conclusion:

Except for the U.S.P. powder, this device is the same glove  
as approved in **K021961**.



APR 17 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

COPIOUMED International, Incorporated  
C/O Ms. Janna P. Tucker  
Official Correspondent  
Tucker & Associates  
198 Avenue De La D' emerald  
Sparks, Nevada 89434-9550

Re: K030927

Trade/Device Name: Powdered Vinyl Examination Gloves, White  
Regulation Number: 880.6250  
Regulation Name: Patient Examination Gloves  
Regulatory Class: I  
Product Code: LYZ  
Dated: March 19, 2003  
Received: March 24, 2003

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner".

Susan Runner, DDS, MA

Interim Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## INDICATIONS FOR USE

**APPLICANT:** COPIOUMED INTERNATIONAL, INC.

**510(k) NUMBER:** K030927

**DEVICE NAME:** POWDERED VINYL EXAM GLOVES,  
WHITE

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)

Chen S. Lim

(Division Sign-Off)

Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

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EXHIBIT B  
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